

Castor oil  
PC Code: 031608

DP Number(s): 402467  
EPA Reg. or File Symbol No: 39775-U



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

**OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION/OFFICE OF PESTICIDE PROGRAMS**

**MEMORANDUM**

**DATE:** 11/27/2012

**SUBJECT:** Science Review in support of registration of Messina Wildlife's Mole Stopper Smoke, containing 14.85% w/w Castor oil as its active ingredient.

<b>Decision Number:</b>	459574
<b>DP Number:</b>	402467
<b>EPA File Symbol Number:</b>	39775-U
<b>Chemical Class:</b>	Biochemical
<b>PC Code:</b>	031608
<b>CAS Number:</b>	8001-79-4
<b>Active Ingredients:</b>	Castor oil
<b>Tolerance Exemptions:</b>	Non-food
<b>MRID Numbers:</b>	487130-01 to 487130-07

**FROM:** Clara Fuentes, Ph.D.  
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**TO:** Cheryl Greene, Regulatory Action Leader  
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**ACTION REQUESTED**

Octavious Hunt Ltd. is requesting registration of a new product, Messina Wildlife's Mole Stopper Smoke, intended for use as a mole repellent underground on lawns, ornamentals, and turf. In support of this action, the registrant is submitting product chemistry data in MRIDs

487130-01, 487130-02 and 487130-03, and providing rationale to satisfy UV/Visible Light Absorption, and Storage stability and Corrosion Characteristics data requirement in MRID 487130-04. The registrant is providing rationale in MRIDs 487130-05 and 487130-07 to satisfy acute mammalian toxicity data requirement, and providing rationale to satisfy required Non-target organism' data requirement in MRID 487130-06. In addition, the registrant submitted copies of product label; CSFs, dated 4/16/12 and 1/6/12; copies of pre-registration meeting minutes, dated 11/23/10, and copies of follow up correspondence between SciReg, Inc. consultants and EPA.

## RECOMMENDATIONS AND CONCLUSIONS

### Product chemistry:

1. Data on Description of the Production Process, Discussion on the Formation of Impurities, Analysis of Samples, and Enforcement Analytical Method are required for the unregistered source of Castor oil **unless** a food grade certification from the supplier of the active ingredient is submitted.
2. The registrant explains that a food-grade source could not be located, and that the BP (British Pharmacopeia)-grade source from the UK (listed as the source of active ingredient on CSF dated 1/6/12) is considered to be equivalent to USP (United States Pharmacopeia)-grade, which is listed as the source of active ingredient on CSF, dated 4/16/12 (Refer to Table 1 under Study Summaries for comparison between BP-grade and USP-grade castor oil).
3. In addition, the registrant states that USP-grade castor oil is considered to be equivalent to food-grade; therefore, a description of the production process, a discussion of the formation of impurities, an analysis of samples, and an enforcement analytical method is not being submitted for an unregistered source of USP-grade castor oil, which is considered to be equivalent to food grade.
4. **The registrant's rationale stating that USP-grade castor oil is considered to be equivalent to food grade needs to be supported by a food grade certification from the supplier of the active ingredient.**
5. The registrant needs to submit a specification sheet and MSDS from the source of active ingredient listed on the CSF, dated 4/16/12. A specification sheet and MSDS from the supplier of for Castor oil BP in UK are provided in MRID 487130-02. The source of active ingredient listed on CSF, dated 4/16/12, however, is not Castor oil BP from a supplier in the UK but Castor oil USP from a supplier in N.J. Therefore, **a specification sheet and MSDS from the supplier of castor oil in N.J. should be provided.**
6. The fuse in the product must be listed as an inert ingredient included on the CSF, and the nominal concentrations and certified limits of the other ingredients, which are within their recommended range, will have to be adjusted as needed to reflect the inclusion of the fuse on the

CSF (Refer to Confidential Appendix for information on product composition, starting materials, and manufacturing process).

7. Two materials (identified in the Starting Materials and Manufacturing Process of the Confidential Appendix) are listed on p. 27 of 43 of the confidential attachment to MRID 487130-02 as used to formulate the product. The description of the formulation procedure however, does not mention these materials. Description of the formulation process should be revised to account for these materials.

8. The registrant has adequately addressed Storage Stability and Corrosion Characteristics for Messina Wildlife's Mole Stopper Smoke. Due to the complexity of castor oil, no appropriate analytical method to determine the percentage of castor oil in the product could be identified. Based on the storage stability and non-corrosive characteristics of the active and inert ingredients in Messina Wildlife's Mole Stopper Smoke, the product is stable and won't corrode its package when stored according to label directions.

9. The registrant has adequately addressed UV/Visible Light Absorption data requirement for castor oil by describing the application method of the product (in pg.4 of MRID 487130-04), and by citing the Agency's conclusion in EPA's Vegetable and Flower Oils Registration Review Summary Document: Initial Docket 2010, that the Agency does not foresee the need to require additional generic product chemistry data.

#### Acute Mammalian Toxicity:

The registrant has adequately satisfied Acute Mammalian Toxicity data requirement with sufficient information on the toxicity of product components (identified in Confidential Appendix). The end-use product however, is designed to release smoke so, any exposure that may occur will be to combustion products, which are identified in the Confidential Appendix, and have not been addressed for toxicity. Therefore, **the registrant's rationale needs to include information on toxicity of, and potential risk from exposure to combustion products as requested at the pre-registration meeting, dated 11/23/2010.**

#### Non-Target organisms:

The registrant has adequately satisfied Non-Target Organisms' data requirement with sufficient information on the toxicity of the active ingredient. **Inert ingredients have not been addressed for toxicity.** Furthermore, the end-use product is designed to release smoke so, any exposure that may occur will be to combustion products, which are identified in the Confidential Appendix, and have not been addressed for toxicity. Therefore, **the registrant needs to include information on toxicity of, and potential risk of exposure to inert ingredients in the product and combustion products.**

## BACKGROUND INFORMATION

The physical form of the end use product is a solid dispenser with a wick that is lit to create smoke in a mole tunnel. The product is a solid packaged in a closed system smoke generator. This system contains 1.09 ounces of formulation packaged in 49 mm x 75 mm tall polyethylene canister with a

fuse that is sealed until use. To use the product, a hole is made in the mole tunnel, the product is then placed in the tunnel with the container lid removed and the fuse lit. Once placed in the tunnel, the hole is covered with earth. Smoke from the product diffuses throughout the tunnel in about 15 to 20 seconds. The surrounding area should be inspected to ensure that all tunnel holes are covered with soil to prevent smoke from leaking out after activation. The empty generator should be removed from the tunnel by the next day after application. One generator is used per 3 mole mounts and will cover up to 40 meters (130 feet) of mole tunnels.

## STUDY SUMMARIES

### Product Chemistry:

Two CSFs are provided. The CSF dated 1/6/2012, gives the source of active ingredient as “Castor Oil BP,” with a supplier in the UK, while the other CSF, dated 4/16/12, gives the source of active ingredient as “Castor Oil USP,” with a supplier in New Jersey. The CSF (dated 1/6/12), specification sheet, and MSDS provided in MRIDs 487130-01 and 487130-02, indicate that the castor oil used to formulate the product complies with British Pharmacopeia (BP) standards, which are similar to USP standards (Table 1). A food-grade source could not be located; however, since the BP-grade source is considered to be equivalent to USP-grade, and USP-grade castor oil is considered to be equivalent to food-grade, the registrant believes that a description of the production process for castor oil is not required. As a result, a description of the production process, a discussion of the formation of impurities, an analysis of samples, and an enforcement analytical method are not submitted for unregistered source of USP-grade castor oil, which is considered to be equivalent to food grade.

<b>TABLE 2. Comparison of BP-grade and USP-grade castor oil</b>		
	<b>BP-grade</b>	<b>USP-grade</b>
Specific gravity	0.952 - 0.965 g/mL	0.957 – 0.961 g/mL
Hydroxyl value	Minimum of 150	160 – 168
Iodine value	82 – 90	83 – 88
Saponification value	176 – 187	176 – 182
Acid value	2 mL maximum	<3.5 mL
Heavy metals	NA	0.001%

Data from p. 3 of 15, MRID 487130-01

The starting materials and manufacturing process to produce Messina Wildlife’s Mole Stopper Smoke are listed on pg. 5 of MRID 487130-02 (Refer to Confidential Appendix for information

of product composition, starting materials and manufacturing process). MSDS for each inert ingredient, and a specification sheet and MSDS for Castor oil BP in UK are provided in MRID 487130-02. The source of active ingredient listed on CSF, dated 4/16/12, however, is not Castor oil BP from a supplier in the UK but Castor oil USP from a supplier in N.J. A specification sheet and MSDS from the supplier in N.J. is not provided.

Registrant's rationale in MRID 487130-04 to satisfy UV/Visible Light Absorption, Storage stability, and Corrosion Characteristics data requirements:

- UV/visible light adsorption data were not required by the Agency for registration review of Vegetables and Flower oils, including castor oil (Initial Docket dated 2010).
- Furthermore, the method of application of Messina Wildlife's Mole Stopper Smoke prevents the product from being exposed to sun light and undergo photochemical degradation.
- The registrant is citing data in the public literature (Merk Index, National Toxicological Program, MSDS and product Specification Sheet) to fulfill the storage stability and corrosion characteristics for castor oil and other inert ingredients (identified in the Confidential Appendix).
- The registrant states in MRID 487130-04 that castor oil is a mixture of fatty acids (approximately 87% ricinoleic, 7% oleic, 3% linoleic, 2% palmitic, 1% stearic, and trace amounts of dihydroxystearic) and thus, an appropriate analytical method to determine the content of castor oil in the product has not been identified.
- Castor oil has excellent keeping qualities (the supplier assigns a one-year minimum shelf life) and is not identified as corrosive.
- Other product components, identified in the Confidential Appendix, are reported as stable under normal conditions of storage, and are non-corrosive.
- Messina Wildlife's Mole Stopper Smoke is packaged in approximately one-ounce individually sealed polyethylene containers that are not to be stored under excessive heat conditions.

**TABLE 2. Physical and Chemical Properties for Castor Oil BP (TGAI) <sup>a</sup>**

Guideline Reference No./Property		Description of Result	Methods
830.6302	Color	Pale yellow to almost colorless	HSDB, Merck Index
830.6303	Physical State	Viscous liquid	HSDB, Merck Index
830.6304	Odor	Faint, mild Slight, somewhat characteristic	HSDB, Merck Index
830.6313	Stability	Excellent keeping qualities, does not turn rancid unless subjected to excessive heat. The TGAI will not come into contact with metals or metal ions.	Merck Index
830.6314	Oxidation/Reduction: Chemical Incompatibility	Not applicable, the product is not expected to be an oxidizing or reducing agent	
830.6315	Flammability	445°F (230°C)	Merck Index
830.6316	Explosibility	Not applicable, the TGAI contains no explosive ingredients	
830.6317	Storage Stability	Excellent keeping qualities, does not turn rancid unless subjected to excessive heat.	Merck Index
830.6319	Miscibility	Not applicable, the product is not an emulsifiable liquid to be diluted with petroleum solvents	
830.6320	Corrosion Characteristics	Excellent keeping qualities, does not turn rancid unless subjected to excessive heat.	Merck Index
830.6321	Dielectric Breakdown Voltage	Not applicable, the product is not for use around electrical equipment	
830.7000	pH	Not applicable, the TGAI is not soluble or dispersible in water	
830.7100	Viscosity	6-8 poises at 25°C (U±½) 259-325 cSt at 37.8°C 98-130 cSt at 54.4°C 986 cP at 293°K	Merck Index Engineering ToolBox Engineering ToolBox <a href="http://www.science.uwaterloo.ca">http://www.science.uwaterloo.ca</a>
830.7200	Melting Range	Not applicable, the product is a liquid	
830.7220	Boiling Range	313°C	HSDB
830.7300	Density/Relative Density/Bulk Density	0.945-0.965 g/mL at 25°C 0.961-0.963 at 15.5°C	HSDB Merck Index
830.7370	Dissociation Constant in Water	Not applicable, the TGAI is insoluble in water	
830.7550	Partition Coefficient	Not applicable, the TGAI is not organic and non-polar and is not soluble in water	
830.7840	Water Solubility	Insoluble	HSDB
830.7950	Vapor Pressure	0 kPa	Engineers Edge

<sup>a</sup>Data from MRID 487130-03

<b>TABLE 3. Physical and Chemical Properties for Messina Wildlife's Mole Stopper Smoke (EP) <sup>a</sup></b>		
<b>Guideline Reference No./Property</b>	<b>Description of Result</b>	<b>Methods</b>
830.6302    Color	Off white (grey)	Self-certification PR Notice 98-1
830.6303    Physical State	Clumped powder	Self-certification PR Notice 98-1
830.6304    Odor	Medium characteristic	Self-certification PR Notice 98-1
830.6313    Stability	Not required for EP	
830.6314    Oxidation/Reduction: Chemical Incompatibility	Not applicable, the product is not expected to be an oxidizing or reducing agent	
830.6315    Flammability	Not applicable, the product is a powder and does not contain combustible liquids	
830.6316    Explodability	Not applicable, the product is a powder and does not contain explosive ingredients	
830.6317    Storage Stability	Waiver requested	
830.6319    Miscibility	Not applicable, the product is not an emulsifiable liquid to be diluted with petroleum solvents	
830.6320    Corrosion Characteristics	Waiver requested	
830.6321    Dielectric Breakdown Voltage	Not applicable, the product is not for use around electrical equipment	
830.7000    pH	Not applicable, the product is not soluble or dispersible in water	
830.7100    Viscosity	Not applicable, the product is a powder	
830.7200    Melting Range	Not applicable, the product is a liquid	
830.7220    Boiling Range	Not required for EP	
830.7300    Density/Relative Density/Bulk Density	1.3 g/cc 1.0 g/cc <sup>b</sup>	Self-certification PR Notice 98-1
830.7370    Dissociation Constant in Water	Not required for EP	
830.7550    Partition Coefficient	Not required for EP	
830.7840    Water Solubility	Not required for EP	
830.7950    Vapor Pressure	Not required for EP	

<sup>a</sup>Data from MRID 487130-03

Acute Mammalian Toxicity (Acute Oral Toxicity; Acute Dermal Toxicity; Acute Inhalation; Acute Eye Irritation; Acute Dermal Irritation; Skin Sensitization Toxicity Data; 90-Day Oral Toxicity in Rats; 90-Day Dermal Toxicity; 90-Day Inhalation Toxicity; Prenatal Development; Bacterial Reverse Mutation Test, and *In Vitro* Mammalian Cell Assays) data requirement:

The registrant is addressing each Acute Mammalian Toxicity data requirement individually with the following rationale:

- The active ingredient in the product is naturally occurring with no toxic mode of action.
- The active ingredient is EPA listed as a Vegetable and Flower oil, approved for use as repellent with a significant history of exposure to humans and the environment.
- According to EPA's February 19, 2010, Preliminary Human Health Assessment for the Registration Review of Vegetable and Flower Oils Memorandum, all of the flower and vegetable oils for which EPA has data on file are classified as Toxicity Category III or IV.
- Castor oil is also on EPA's list of minimal risk substances (FIFRA Section 25(b)).
- Two inerts are on EPA's list of minimal risk substances (FIFRA Section 25(b)) and have a history of safe use. One of them is commonly consumed as food commodity (Refer to Confidential Appendix for identity of formulation components).
- The third inert belongs to a group classified as Toxicity Category III (Refer to Confidential Appendix for identity of formulation components).

Non-target Organisms' (Avian Acute Oral Toxicity, Avian Dietary Toxicity, Fish Acute Toxicity, Aquatic Invertebrate Acute Toxicity, Seedling Emergence, Vegetative Vigor, and Nontarget Insects) data requirement:

The registrant is addressing each Non-Target Organisms' data requirement individually with the following rationale:

- The active ingredient in the product is naturally occurring with no toxic mode of action.
- The active ingredient is EPA listed as a Vegetable and Flower oil approved for use as repellent with a significant history of exposure to humans and the environment.
- Castor oil is also on EPA's list of minimal risk substances (FIFRA Section 25(b)).



- The Vegetable and Flower Oils Final Work Plan, dated September 20, 2010, concludes that: a) there are no concerns of adverse exposure to non-target terrestrial and aquatic organisms by end-use products containing vegetable and flower oils; b) vegetables and flower oils are
- not toxic to non-target insects, and c) castor oil products will have “no effect” on any currently listed threatened or endangered species, or on any designated critical habitat. According to The Vegetable and Flower Oils Final Work Plan, dated September 20, 2010, the Agency does not foresee the need for additional ecotoxicity data or a new risk assessment.

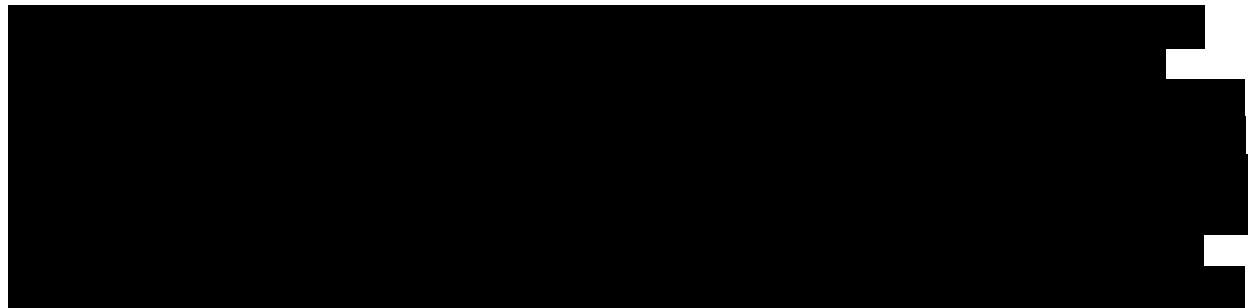
cc: *Clara Fuentes, RALCheryl Greene*, BPPD Chron File, IHAD/ARS  
FT, PY-S: 11/27/12

## CONFIDENTIAL APPENDIX

TABLE 1. Nominal concentration and certified limits for Messina Wildlife’s Mole Stopper Smoke <sup>a</sup>					
Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Castor oil USP (8001-79-4)	031608	Active ingredient	14.85	14.11	15.59
Inert Ingredients					

<sup>a</sup>Data from CSF dated 4/16/12

### Starting Materials and Manufacturing Process:



\*Inert ingredient information may be entitled to confidential treatment\*

\*Manufacturing process information may be entitled to confidential treatment\*

\*Inert ingredient information may be entitled to confidential treatment\*

\*Manufacturing process information may be entitled to confidential treatment\*